

Remarks/Arguments

The foregoing amendments to the claims are of formal nature, and do not add new matter. Claims 119-131 are pending in this application and are rejected on various grounds. Claims 119-124 have been amended with a functional recitation: "wherein said polypeptide induces chondrocyte redifferentiation". Further, all pending claims have been amended to remove references to "Figures" and to "the extracellular domain lacking its associated signal peptide". Claim 128 has been canceled without prejudice or disclaimer. The rejections to the presently pending claims are respectfully traversed.

Priority

Applicants rely on the 'chondrocyte redifferentiation' assay for patentable utility of this case, first disclosed in International Application PCT/US/00/08439, filed March 30, 2000, priority for which has been claimed in this application. The Examiner acknowledges utility for this molecule based on the chondrocyte redifferentiation assay in U.S. application No. 09/941,992. For the same reasons, Applicants submit that the subject matter defined in International Application PCT/US/00/08439 (as SEQ ID No: 422; Figure 304) also provide specific and substantial and a well established utility for the claimed invention in the present application. Hence, the present application is at least entitled to an effective filing date of **March 30, 2000**.

Specification

The specification has been amended to delete all "embedded hyperlink and/or other forms of browser-executable code" and to correct minor errors. Their entry is respectfully requested. No new matter has been added due to these amendments.

Information Disclosure Statement

The Examiner had objected to the previously submitted IDS because it did not comply with the requirements of 37 C.F.R. § 1.98(a)(2). Applicants hereby submit a new IDS separately enlisting each accession number for the sequence, the reference and the database where the

sequence is available, from the previously submitted Blast report of 5/31/2002 which complies with 37 C.F.R. § 1.98(a)(2). Consideration of this Information Disclosure Statement is respectfully requested.

Claim Rejections – 35 USC § 112, first paragraph

Claims 119-124, 127-128 and 130-131 are rejected under 35 U.S.C. §112, first paragraph while being enabled for an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 422, does not reasonably provide enablement for an isolated polypeptide having at least 80%-99% identity to the polypeptide of SEQ ID NO: 422.

Claim 128 has been canceled without prejudice or disclaimer. Applicants respectfully disagree with and traverse the rejection to the remaining claims.

The instant invention, as amended, is now defined by polypeptides having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 422 that recite the functional recitation: "wherein said polypeptide induces chondrocyte redifferentiation." Thus, the pending claims are now drawn to a genus of polypeptides defined both by sequence and functional identity and only those variants that test positive in the chondrocyte redifferentiation assay are encompassed by these claims.

The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. Specific utility has been asserted in the present invention based on the well-established assay "chondrocyte redifferentiation assay." It would have been obvious to one skilled in the art at the effective priority date, in view of Applicant's possession of the PRO1387 sequence (SEQ ID NO: 422), that the Applicant possessed obvious variations and adaptations of SEQ ID NO: 422 as well, at the time of filing. To prepare such mutants is routine in the art, and the positions at which the mutations occur are irrelevant, so long as they test positive in the chondrocyte redifferentiation assay. Preparing such mutants and running these polypeptides through the well-defined assay, as defined in detail in the specification would be

routine and is not considered undue. Hence, Applicants request that the present rejection to the present claims be reconsidered and withdrawn.

Claim Rejections - 35 USC § 112, first paragraph -written description

Claims 119-123, 124, 127, 128 and 130-131 are rejected under 35 U.S.C. 112, first paragraph because allegedly, the subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time of filing.

Whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

As discussed above, the instant invention, defined by the claims, concerns polypeptides having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed polypeptide sequence SEQ ID NO: 422 with the functional recitation: "wherein said polypeptide induces chondrocyte redifferentiation." The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. Specific utility has been asserted in the present invention based on the well-established assay "chondrocyte redifferentiation assay." It would have been obvious to one skilled in the art at the effective priority date, in view of Applicant's possession of the PRO1387 sequence (SEQ ID NO: 422), that the Applicant possessed obvious variations and adaptations of SEQ ID NO: 422 as well, at the time of filing based on the disclosure of the well-established assay in the specification.

Hence, Applicants request that the present rejection to the present claims be reconsidered and withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

Claims 119-124 and 128-131 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which the applicant regards as the invention. The Examiner rejects the term "the extracellular domain lacking its associated signal sequence".

References to this term and claim 128 have been canceled. Accordingly, this rejection is moot and should be withdrawn.

Claim Rejections – 35 USC § 102

a. Claims 119-131 are rejected under 35 U.S.C. §102(b) as being anticipated by as being anticipated by Baker *et al.* (WO 99/63088, dated 9 December/1999).

Based on the discussions above, Applicants believe that they are entitled to at least an effective date of **March 30, 2000** for this application. Accordingly, WO 99/63088, dated December/1999 is **102(a)** art instead. Applicants further submit that WO 99/63088, dated December/1999 is the Applicants own art and can be overcome with an affidavit if necessary. Applicants also submit that the nucleic acids and polypeptides of SEQ ID NO: 422 and 421 were cloned, sequenced and disclosed in U.S. provisional application 60/097978, filed 8/26/1998 as SEQ ID NOs: 2 and 1 (Figures 2 and 1) respectively and priority has been claimed to this provisional application. If necessary, a Declaration can be submitted to reiterate this point.

Accordingly, Applicants submit that the above cited art is not prior art and this rejection should be withdrawn.

b. Claims 119-131 are rejected under 35 U.S.C. §102(b) as being anticipated by Ashkenazi *et al.*, dated (published 8 June 2000).

Based on the discussions above, Applicants believe that they are entitled to at least an effective date of **March 30, 2000** for this application, which predates the publication date for Ashkenazi. Accordingly, the above cited reference is not prior art and this rejection should be withdrawn.

c. Claims 119-125, 130 are rejected under 35 U.S.C. §102(b) as being anticipated by Walker *et al.*, dated (published 25 May 2000).

Based on the discussions above, Applicants believe that they are entitled to at least an effective date of **March 30, 2000** for this application, which predates the publication date for Walker. Accordingly, the above cited reference is not prior art and this rejection should be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-2730P1C46). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: December 30, 2004

By:


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